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10/538,135	06/09/2005	Maosheng Duan	PU5020USw	5458	
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CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398			MABRY, JOHN		
	H TRIANGLE PARK, NC 27709-3398		ART UNIT	PAPER NUMBER	
			1625		
			NOTIFICATION DATE	DELIVERY MODE	
			10/29/2008	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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	Application No.	Applicant(s)	
	10/538,135	DUAN ET AL.	
Office Action Summary	Examiner	Art Unit	
	John Mabry, PhD	1625	
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address	
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim 11 apply and will expire SIX (6) MONTHS from 12 cause the application to become ABANDONEI	I. ely filed the mailing date of this communio O (35 U.S.C. § 133).	
Status			
1) Responsive to communication(s) filed on			
	-· action is non-final.		
3) Since this application is in condition for allowan		secution as to the meri	ts is
closed in accordance with the practice under <i>E</i>			10 10
ologod in accordance with the practice and in	x parte quayre, 1000 0.D. 11, 10	0 0.0. 210.	
Disposition of Claims			
4) ☐ Claim(s) <u>1,6-8,11,15-18,20,21 and 34-36</u> is/are 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) <u>1,6-8,11,15-18,20,21 and 34-36</u> is/are 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	vn from consideration.		
Application Papers			
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examiner	epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.1	` '
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Application ity documents have been received (PCT Rule 17.2(a)).	on No d in this National Stage	3
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6/9/05.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	te	

Application/Control Number: 10/538,135

Art Unit: 1625

DETAILED ACTION

Page 2

Examiner's Response

Applicant's response on July 31, 2008 filed in response to the Election/Restriction dated June 6, 2008 has been received and duly noted. The Examiner acknowledges Applicants' election of Group I with traverse. The Applicant clarified Examiner's Restriction Requirement as follows:

X = C1-5 alkylene not alkyl

R9 = alky as well as H.

Thus, the restriction requirement is deemed proper and **FINAL**.

In view of this response, the status of the rejections/objections of record is as follows:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-8, 11, 15-18, 20-22 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant claims compounds of the following formula:

Art Unit: 1625

Where ring A is selected from:

According to structure of Formula I, substituent R2 can be located at any position on ring A. Applicant specifies where substituent R2 can be placed on tropanyl ring by indicating an asterisk (*). Nowhere does Applicant indicate the position of substituent R2 on the claimed piperidinyl ring. Can R2 be located at any position on ring A of piperidinyl ring as indicated by Formula I or is piperidinyl not substituted (by Applicant's lack of asterisk)?

Claims 1, 6-8, 11, 15-18, 20-22 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" in corresponding claims is a relative term which renders the claim indefinite. The term "derivative" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What does Applicant intend for this term to mean? This term has no limitations, thus encompassing all structural possibilities.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Page 4

Claims 1, 6-8, 11, 15-18, 20-22 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for salts, does not reasonably provide enablement for hydrates and solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to hydrates and solvates. But the numerous examples presented all failed to produce a hydrate or solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

Claims 1, 6-8, 11, 15-18, 20-22 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

R2 being substituents as in illustrated in examples in specification;

R9 being unsubstituted alkyl (more specifically methyl = R7 being H);

R3 being as in illustrated in examples in specification, but

does not reasonably provide enablement for all possibilities as claimed for:

Art Unit: 1625

R2=

R² is independently selected from -OR⁰, -C(O)-R⁰, -S(O)₂-R², -C(O)-N(R³)₂, -S(O)₂-N(R³)₂, -(CH₂)_a-N(R⁵)(-V_b-R⁺), -(CH₂)_a-(-V_b-R⁺), halogen, alkyl optionally substituted by one or more R⁷, alkynyl optionally substituted by one or more R⁷, aryl optionally substituted by one or more R⁸, heteroaryl optionally substituted by one or more R⁸, cycloalkyl optionally substituted by one or more R⁸, and heterocyclyl optionally substituted by one or more R⁸; and two adjacent R²s on Ring A are optionally taken together to form a fused, saturated, partially saturated or aromatic 5-6 membered ring having 0-3 heteroatoms selected from oxygen, phosphorus, sulfur,

or nitrogen; or two geminal R²s are optionally taken together to form a spiro, saturated, partially saturated or aromatic 5-6 membered ring having 0-3 heteroatoms selected from oxygen, phosphorus, sulfur, or nitrogen, said fused or spiro ring being optionally substituted by one or more R⁸;

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a is 0-3;
b is 0 or 1;
V is -C(O)-, -C(O)O-, -S(O)<sub>2</sub>-, or -C(O)-N(R<sup>9</sup>)-;
R* is alkyl, cycloalkyl, aralkyl, aryl, heteroaryl, heteroaralkyl, or heterocyclyl, wherein said R* is optionally substituted by one or more R<sup>8</sup>;
d is 0-1;
m is 9-or 1;
n is 0-5:
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R7=

 R^7 is independently selected from halogen, CF_3 , $\mathsf{-R}^0$, $\mathsf{-OR}^0$, $\mathsf{-OCF}_3$, $\mathsf{-(CH_2)_{1:6}}\mathsf{-OR}^0$, $\mathsf{-SR}^0$, $\mathsf{-SCF}_3$, $\mathsf{-(CH_2)_{1:6}}\mathsf{-SR}^0$, aryl optionally substituted by $\mathsf{-R}^6$, methylenedioxy, ethylenedioxy, $\mathsf{-NO}_2$, $\mathsf{-CN}$, $\mathsf{-(CH_2)_{1:6}}\mathsf{-CN}$, $\mathsf{-N(R^0)_2}$, $\mathsf{-NR^0C(O)R^0}$, $\mathsf{-NR^0(CN)}$, $\mathsf{-NR^0C(O)N(R^0)_2}$, $\mathsf{-NR^0NR^0CO_2R^0}$, $\mathsf{-NR^0NR^0CO_3R^0}$, $\mathsf{-NR^0NR^0CO_3R^0}$, $\mathsf{-CO)CO(O)R^0}$, $\mathsf{-CO)CO(O)R^0$, $\mathsf{-CO)CO(O)R^0}$, $\mathsf{-CO(O)R^0}$, \mathsf

saturated, or aromatic ring having additional 0-4 heteroatoms selected from oxygen, phosphorus, nitrogen, or sulfur;

each R^8 independently is selected from the group consisting of R^7 , =0, =\$, =N(R^0), and =N(CN);

R3=

 R^3 independently is -H, -N(R°)₂, -N(R°)C(O)R°, -CN, halogen, -CF₃, alkyl optionally substituted by one or more groups selected from R^7 or -S-aryl optionally substituted by -(CH₂)₁₋₈-N(R°)SO₂(R°), alkenyl optionally substituted by one or more groups selected from R^7 or -S-aryl optionally substituted by -(CH₂)₁₋₈-N(R°)SO₂(R°), alkynyl optionally substituted by one or more groups selected from R^7 or -S-aryl optionally substituted by -(CH₂)₁₋₈-N(R°)SO₂(R°), cycloalkyl or carbocyclyl optionally substituted by one or more R^8 , aryl optionally substituted by one or more R^8 , aryl optionally substituted by one or more R^8 , or heterocyclyl optionally substituted by one or more R^8 .

Page 7

or list any reagents wherein compounds can be used to synthesis compounds as listed above.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(1) Breadth of claims: Scope of the compounds. Owing to the range of many variables, millions of highly substituted cyclohexyl piperidinyl and cyclohexyl tropanyl compounds are embraced.

(2) The nature of the invention: The invention is a highly substituted cyclohexyl piperidinyl and cyclohexyl tropanyl compounds.

- (3) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and chemical reactivity (which is affected by determinants such as substituent effects, steric effects, bonding, molecular geometry, etc) is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).
- (4) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of application's general formula I. Pages 39-69 of the Specification describes starting materials and methods for synthesis of compounds wherein R2, R3, R7 and R9 as mentioned, but does not describe or list any reagents wherein compounds can be used to synthesis compounds the full scope of claimed chemical moieties, functional groups and substituents as listed above. There is limited evidence in the Specification of the example compounds that only covers no or a small portion of the substituents claimed of formula I. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in Scope.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 2164.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or

apparatus necessary to a make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court *in re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(5) State of the Prior Art: These compounds are substituted cyclohexyl piperidinyl and cyclohexyl tropanyl compounds which discloses compounds of Formula I where X=-CH2-, A=-N-piperidinyl, n=0, R10=phenyl, d=0, R1=-NR9(Y)m-R3 wherein R9=H, Y=-C(O)- and R3=alkyl substituted by phenyl, which are well documented in the art as described by Pineiro. So far as the examiner is aware, no substituted containing the full scope as Applicant's claimed of any kind have been made or used.

It is not trivial to experimentally interchange any and all of the many substituents that exist. As generally described by F. Zaragoza Dörwald, most organic syntheses fail initially and chemical research is highly inefficient due to chemists spending most of their time "finding out what went wrong and why". Therefore, most syntheses of organic compounds are labor-intensive and demanding. Additionally, most final synthetic routes

to desired organic molecules are usually very different from initially planned routes. A highly skilled chemist can agree that for many successful organic compounds made, many failures are encountered and experimental repetition is common. This also contributes to the burden and unpredictability of the syntheses of said compounds. (see "Side Reactions in Organic Synthesis: A Guide to Successful Synthesis Design" 2005 Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim.

- (6) Working Examples: Applicant shows examples 39-69 but no working examples were shown wherein R2, R3, R7 and R9 equal aforementioned scope have been made or used of any kind.
- (7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.
- (8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*,

999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 6-8, 11, 15-18, 20-21 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pineiro et al (US 7,105,507).

The instant application claims compounds of Formula I where X=-CH2-, A=-N-piperidinyl, n=0, R10=phenyl, d=0, R1=-NR9(Y)m-R3 wherein R9=H, Y=-C(O)- and R3=alkyl substituted by phenyl.

Art Unit: 1625

Scope & Content of Prior Art MPEP 2141.01

Pineiro discloses compounds of Formula I where X=-CH2-, A=-N-piperidinyl, n=0, R10=phenyl, d=0, R1=-NR9(Y)m-R3 wherein R9=H, Y=-C(O)- and R3=alkyl substituted by phenyl (see Example 48, column 96).

Differences between Prior Art & the Claims MPEP 2141.02

Pineiro differs from the instant application at the position of R10: Pineiro's phenyl at the 4-position on the cyclohexyl ring versus Applicant's phenyl at the 1-position of the cyclohexyl ring. These are considered positional isomers.

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

There is little difference between the phenyl at the 4-position on the cyclohexyl ring versus phenyl at the 1-position of the cyclohexyl ring on the claimed structure of formula I. It is well established that position isomers are prima facie structurally obvious even in the absence of a teaching to modify. The isomer is expected to be prepared by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing the position isomers. This circumstance has arisen many times. See: *Ex parte Englehardt*, 208 USPQ 343, 349; *In re Mehta*, 146 USPQ 284, 287; *In re Surrey*, 138 USPQ 67; *Ex Parte Ullyot*, 103 USPQ 185; *In re Norris*, 84 USPQ 459; *Ex. Parte Naito*, 168 USPQ 437, 439; *Ex parte Allais*, 152 USPQ

66; In re Wilder, 166 USPQ 545, 548; Ex parte Henkel, 130 USPQ 474; Ex parte Biel, 124 USPQ 109; In re Petrzilka, 165 USPQ 327; In re Crownse, 150 USPQ 554; In re Fouche, 169 USPQ 431; Ex parte Ruddy, 121 USPQ 427; In re Wiechert, 152 USPQ 249, In re Shetty, 195 USPQ 753; In re Jones, 74 USPQ 152, 154. There may be others as well. Thus, said claims are rendered obvious by Pineiro et al.

For example, "Position isomerism has been used as a tool to obtain new and useful drugs" (Englehardt) and "Position isomerism is fact of close structural similarity" (Mehta, emphasis in the original). Note also In re Jones, 21 USPQ2d 1942, which states at 1943 "Particular types or categories of structural similarity without more, have, in past cases, given rise to prima facie obviousness"; one of those listed is "adjacent homologues and structural isomers". Position isomers are the basic form of close "structural isomers." Similar is *In re Schechter and LaForge*, 98 USPQ 144, 150, which states "a novel useful chemical compound which is homologous or isomeric with compounds of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compounds." Note also In re Deuel 34 USPQ2d 1210, 1214 which states, "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds...a known compound may suggest it analog or isomers, either geometric (cis v. trans) or position isomers (e.g. ortho v. para)." See also MPEP 2144.09, second paragraph. Further, the reference provides for the ring being substituted in any position.

Pineiro also discloses the following compounds. The instant claims are deemed obvious in over Pineiro for the reason described in above rejection.

$$F_{3}C$$

$$\downarrow \qquad \qquad \downarrow \qquad \qquad \qquad \downarrow \qquad \qquad \qquad \downarrow \qquad \qquad \qquad \downarrow \qquad \qquad \qquad$$

Art Unit: 1625

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-8, 11, 15-18, 20-21 and 34-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of copending Application No. 2006/0229336 (10/538,144) and claims 1-24 and 37-39 of copending Application No. 2006/0052595 (10/538,145). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

2006/0229336 (10/538,144) and 2006/0052595 (10/538,145) claim compounds of Formula I where X=-CH2-, A=-N-piperidinyl, n=0, R10=phenyl, d=0, R1=-NR9(Y)m-R3 wherein R9=H, Y=-C(O)- and R3=alkyl substituted by aryl and heteroaryl.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 6-8, 11, 15-18, 20-21 and 34-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12

of U.S. Patent No. 7,271,172 (10/538,134). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

7,271,172 (10/538,134) claims compounds of Formula I where X=-CH2-, A=-N-piperidinyl, n=0, R10=phenyl, d=0, R1=-NR9(Y)m-R3 wherein R9=H, Y=-C(O)- and R3=alkyl substituted by aryl and heteroaryl.

Conclusion

Applicant is respectfully reminded that it is <u>required</u> that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor,

Art Unit: 1625

Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/ Examiner Art Unit 1625

> /Rita J. Desai/ Primary Examiner, Art Unit 1625